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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/058,495 | 01/28/2002 | Richard King | 265280-68002 | 2189 |

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INDIANAPOLIS, IN 46204

EXAMINER

RAMANA, ANURADHA

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3732

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,495

Applicant(s)

KING ET AL.

Examiner

Anu Ramana

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-63 and 124 is/are pending in the application.
- 4a) Of the above claim(s) 53,54,62 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-52,55-61 and 124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49-52, 55-61 and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by McKellop et al. (US 6,165,220).

Regarding claims 49-52 and 55, McKellop et al. disclose an implantable bearing or acetabular cup with a crosslinked ultra high molecular weight polyethylene (UHMWPE) surface or “first” layer functioning as the bearing or articulating surface and an underlying or “second” non-crosslinked layer which has an engaging surface for attachment to the acetabulum of a patient wherein the two layers are compression molded (Figure 2, col. 2, lines 19-22, col. 3, lines 14-19, col. 9, lines 34-67 and col. 10, lines 1-19).

Regarding claims 56-61, McKellop et al. further disclose another embodiment wherein the crosslinking gradually diminishes below the surface layer, i.e., the surface layer has a degree of crosslinking while the underlying layer has a different degree of crosslinking (col. 4, lines 56-67 and col. 5, lines 1-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49-52, 55-61 and 124 are rejected in the alternative under 35 U.S.C. 103(a) as being unpatentable over McKellop et al. (US 6,165,220) in view of Tukachinsky et al. (US 6,652,943).

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McKellop discloses each and every structural element of Applicants' claimed invention. See previous discussion of McKellop.

McKellop further discloses crosslinking of a polymer layer utilizing radiation such as an electron beam (col. 2, lines 18-31).

Tuckachinsky teaches the equivalence of gamma rays and electron beams in order to achieve polymer crosslinking (col. 6, lines 60-65).

Therefore, even if "gamma radiation" results in different structural characteristics of the bearing than "electron beam radiation", it would still have been prima facie obvious at the time the invention was made to have utilized a "gamma irradiated crosslinked layer of polymer" in the McKellop bearing since Tuckachinsky teaches that gamma irradiation is a recognized technique for polymer crosslinking.

Response to Arguments

Applicant's arguments with respect to claims 49-52 and 55-61 submitted under "REMARKS" in the response filed on June 28, 2004 have been fully considered but are not persuasive.

Claims 49-52, 55-61 and new claim 124 are product-by-process claims. Product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on the method of its production. If the product in the product-by-process claim is the same as or obvious from the product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicants could overcome the anticipation rejection by providing evidence that the product limitation "gamma irradiated crosslinked layer of polymer" or "gamma irradiated polymer" imparts a distinctive structural characteristic to the bearing of Applicants' claimed invention.

A statement or argument by the Attorney is not factual evidence (MPEP 716.01).

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Regarding Applicants' statement that McKellop does not disclose a "non-crosslinked layer of polymer molded to said crosslinked layer of polymer," the Examiner directs Applicants' attention to col. 9, lines 58-63 and Fig. 2 of McKellop where it is clearly stated and shown that the non-crosslinked layer and the crosslinked layer are molded to form the bearing.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*
October 31, 2004


EDUARDO C. ROBERT
PRIMARY EXAMINER